5. Documentation of the Clinical Database

5.a. Clinical Database Design Structure

There are 21 tables in the Clinical database; 6 of which are system tables (stbl) and 15 are simple database tables (tbl). There are 34 queries; 32 of which are simple database queries (qry) and 2 are system queries (zqry). There are also 18 forms, 9 reports, and 6 modules. Information on the study cases/controls is recorded in the clinical database screens, which are found throughout the 18 forms of the Clinical database. The tables of the Clinical database differ than those of the CATI. Some tables list the "LUGroup" which is a field name given for where certain items are grouped together, while the form screen under the database's "Properties" indicates the "Control Source" to be a field name. The "LUItem" is the code given for the responses; or response code. The "LUValue" is the response options for the items.

For some items, the response codes are listed under queries instead of tables; and sometimes they are listed under both queries and the master table: stblLookupLists under a specific "LUGroup". Checkbox answers are given the standard database values (response codes) of "-1" is true/yes and "0" is false/no. If the box is checked, that equals yes or true and it is given a value of "-1". The checkbox values are not given in any specific table in the Clinical Database. The "option group" (also known as "Radio Buttons") allows for only one answer choice to be checked/selected. Like the checkbox option, it is a standard database feature and has no tables or response codes linked to it. However, unlike the checkbox answers, the database does not provide a "-1" or a "0" response code/value for the option group/radio button; but a different number corresponding to each separate response/choice. Text responses indicate the information (even if it is a number) is imputed manually and there is no response code for it found in the tables. It is regarded as a text answer.

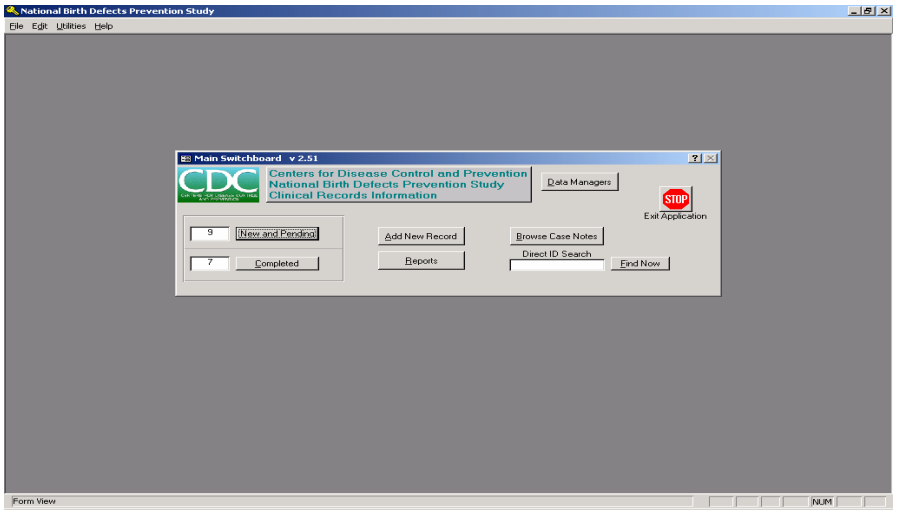
5.b. Table to Form Connections

5.b.i. Relation Between Tables (Pending)

5.c. Clinical Database Documentation by Content Area

The Main Switchboard screen has the following: "New and Pending", "Completed", "Add New Records", "Reports", "Browse Case Notes", and a blank space for a "Direct ID Search". It also has a "Data Managers" button designed for data managers to access and an "Exit Application" button in a red hexagon stop sign to leave/end the Clinical database.

The "Data Managers" access button includes a blank space for the data manager to specify which study ID to be deleted, another blank space for reconfirmation of the study ID to be deleted, and the study ID's date of birth. It also has a "Delete Now" button and a "Cancel" button.



In certain sections of the Clinical Database, the terms “ICD-9” codes and “NBDPS” codes will appear. The “ICD-9” codes (or “ICD-9 CM” codes) will refer to the International Classification of Diseases – 9th Revision, Annotated Edition, Clinical Modification –Volume 1 (WHO, October 1989). The “NBDPS” codes apply to the NBDPS study only and are more defect-specific than ICD-9 codes. The “ICD-9” codes are a 4-digit code; the “ICD-9 CM” codes are a 5-digit code; the “NBDPS” codes are a 6-digit code classified as “eligible” and “non-eligible”.

5.c. Clinical Database

The Study ID number as well as the checkbox “Completed Status” field appear in the “New and Pending” as well as the “Completed” screens; under all of their sections/tabs. Status of “new” cases is automatically checked once the new case page is opened. The study manager or clinical reviewer checks statuses of cases such as “pending”, pending and ready for interview “and” complete. The type of date recorded is also an option that is automatically checked once the date is recorded.

When information is from the tracking system regarding a case is entered, the case is considered to be a “new” case. When the study coordinator inputs the information, the case is considered to be a “pending” case; at this point, case eligibility is not determined until the clinical geneticist has reviewed the case. After the CDC clinical reviewer reviews the case and more information is needed, the case status is updated (see response options below). The case becomes “complete” (or it is classified as “Not a NBDPS Case”) after it has been reviewed and no additional information is needed.

Case Status:

Response	**Description**
1	New
2	Pending
3	Pending, Ready for Interview
4	Completed

Table Name: stblLookupLists
LUGroup: CaseStatus

There are two categories for date type in the Clinical Database. A "Date Data Type" corresponds to when the entire date (month, day, and year) is manually entered in one single field (i.e.: "Mother's Birth Date" is given as "*mm/dd/yyyy"* in one field). A "Three Part Date" corresponds to when the date is entered in three separate fields (i.e.: "EDD" –expected delivery date- is given as "*mm* "in the month field, "*dd"* in the day field, and "*yyyy"* in the year field). The "Three Part Date" provides a pull-down lists for each field.

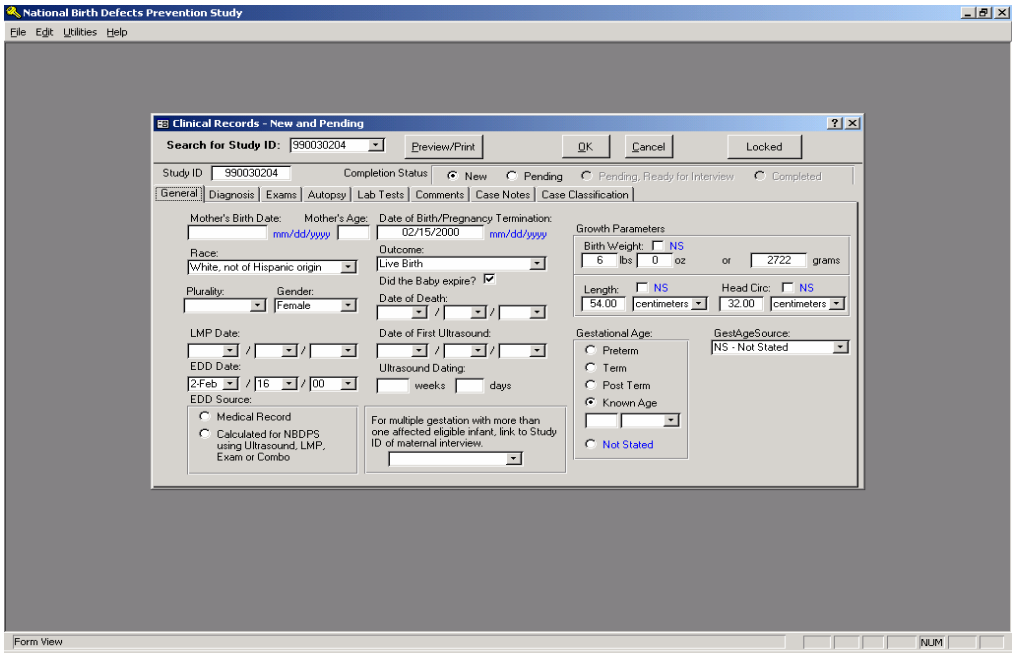
Date Type:

Response	**Description**
1	Date Data Type
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

5.c.i. Section A: "New and Pending" and "Completed"

The "New and Pending" button leads to the "Clinical Records –New and Pending" screen. Where the data manager can search for a new and pending study ID number. There are 8 tabs shown for cases that lead to other screens within the "New and Pending" and the "Completed" screens: "General", "Diagnosis", "Exams", "Autopsy", "Lab Tests", "Comments", "Case Notes", and "Case Classification". For controls, only 3 tabs are shown: "General", "Case Notes", and "Case Classification". All of these screens will show the "Search for Study ID" field, the "Study ID" field, the "Preview/Print" button (displays a print preview of the detailed report on the current selection. This report contains all of the information collected on a case/control. Once viewed, it can be printed from the "File" menu or by right-clicking on the report), the "DupDxCode" button which leads to a table where one can check for duplicate diagnosis codes, the "OK" button, the "Cancel" button, the "Locked" button and the "Completion Status" field which marks the case is "new" or "pending" from the options: "New", "Pending", "Pending/Ready for Interview", or "Completed".



5.c.i.1. General

The "General" screen includes information on mother's and index baby's birth date, race, outcome, plurality, gender, mother's LMP date ("last menstrual period"), EDD date ("expected delivery date") and source (obtained from medical record or calculated), date of first ultrasound, index baby's growth parameters, gestational age, and gestational age source. The field where a study ID can be linked is for cases where siblings are involved in the study. Information on date of birth, outcome, and gender are obtained from the tracking system tool where each case is initially recorded and assigned a NBDPS study ID. All other information needs to be added from the information obtained from abstractors or vital records.

Search for Study ID:

Response	Description
Number	Study ID Number

Query Name: qryCaseList

Note: The Study ID Number is a 9-digit number that corresponds to the following:

1st and 2nd digits:	Location Identifier (represents the Center number)
3rd and 4th digits:	Case Birth Year (birth year of Case or Control)
5th digit:	Case/Control Identifier (Case = 1, Control = 2, Practice/Test = 3)
6th to 9th digits:	Unique Sequential Identifier (unique number given to each Case or Control. It is sequentially incremented and it is reset back to "0001" at the start of each year).

Mother's Birth Date: *(mm/dd/yyyy)*

Response	Description
MM/DD/YYYY	Month/Day/Year

Control Name: MotherBDay

Date Type:

Response	Description
1	Date Data Type

Table Name: stblLookupLists
LUGroup: DateType

Mother's Age:

Note: Age determined by Mother's Birth Date minus Child's Birth Date.

Date of Birth/Pregnancy Termination: *(mm/dd/yyyy)*

Response	Description
MM/DD/YYYY	Month/Day/Year

Control Source: BirthDate

Date Type:

Response	Description
1	Date Data Type

Table Name: stblLookupLists
LUGroup: DateType

Race:

Response	Description
1	White, not Hispanic
2	Black, not Hispanic
3	Asian, Pacific Islander
4	Native American or Alaskan Native
97	NS- Not Stated
6	Hispanic
5	Other
7	DK

Table Name: stblLookupLists
LUGroup: Race

Outcome:

Response	Description
1	Live Birth
2	Fetal death >= 20 weeks (Stillbirth)
3	Induced Abortion
4	Fetal death < 20 weeks (Excluded)

Query Name: qryOutcome_Case

"Did the baby expire?"

Response	Description
Check box	True/False
-1	Yes (true)
0	No (false)

Date of Death: (if the baby expired)

Response	Description
MM	Month
1	January
---	---
12	December
90	Beginning of year
91	Middle of year

92……End of year
97……NS- Not Stated

Table Name: stblLookupLists
LUGroup: MonthList

Response	Description
DD	Day
1	1st day
---	---
31	31st day
90	Beginning of month
91	Middle of month
92	End of month
97	NS- Not Stated

Table Name: stblLookupLists
LUGroup: DayList

Response	Description
YYYY	Year
1996	1996
---	---
2003	2003
97	NS- Not Stated

Table Name: stblLookupLists
LUGroup: YearList

Date Type:

Response	Description
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

Plurality:

Response	Description
1	Single
2	Twin
3	Other multiple birth
9	DK

Table Name: stblLookupLists
LUGroup: Plurarity

Gender:

Response	Description

1……..…Male
2……..…Female
3……..…Ambiguous
97……NS- Not Stated

Table Name: stblLookupLists
LUGroup: Gender

LMP Date:

Response	Description
MM	Month
1	January
---	---
12	December
90	Beginning of year
91	Middle of year
92	End of year
97	NS- Not Stated

Query Name: qryMonthList

Response	Description
DD	Day
1	1st day
---	---
31	31st day
90	Beginning of month
91	Middle of month
92	End of month
97	NS- Not Stated

Query Name: qryDayList

Response	Description
YYYY	Year
1996	1996
---	---
2003	2003
97	NS- Not Stated

Query Name: qryYearList

Date Type:

Response	Description
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

Date of First Ultrasound:

Note: Response codes, descriptions, and query names for date values are the same as the ones listed above in "LMP Date".

Month:
Query Name: qryMonthList

Day:
Query Name: qryDayList

Year:
Query Name: qryYearList

Date Type:

Response	Description
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

EDD Date:

Note: Response codes, descriptions, and query names for date values are the same as the ones listed above in "LMP Date".

Month:
Query Name: qryMonthList

Day:
Query Name: qryDayList

Year:
Query Name: qryYearList

Date Type:

Response	Description
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

Ultrasound Dating:

Response	Description
Text	Age (weeks) determined by the first ultrasound.
Text	Age (days) in addition to ultrasound weeks.

EDD Source:

Response	Description
11	Medical Record
12	Ultrasound, LMP, Exam or Combo

Table Name: stblLookupLists
LUGroup: EDDSource

Growth Parameters- Birth Weight:

Response	Description
Check box	True/False NS- Not Stated
-1	Yes (true)
0	No (false)
Text	Number:
Text	Birth weight in pounds (lbs)
Text	Birth weight in ounces (oz)
Text	Birth weight in grams

Growth Parameters- Length:

Response	Description
Check box	True/False NS- Not Stated
-1	Yes (true)
0	No (false)
Text	Number
1	Inches
2	Centimeters

Table Name: stblLookupLists
LUGroup: LengthUnit

Growth Parameters- Head Circumference:

Response	Description
Check box	True/False NS- Not Stated
-1	Yes (true)
0	No (false)
Text	Number
1	Inches
2	Centimeters

Table Name: stblLookupLists
LUGroup: LengthUnit

Gestational Age:

Response	Description

Checkbox 1……Preterm
Checkbox 2……Term
Checkbox 3……Post Term
Checkbox 4……Known Age*
Checkbox 5……Not Stated

Table Name: stblLookupLists
LUGroup: GestAgeOption

***Note:** If a "known age" is selected, then the number of weeks is entered. A gestational age with a decimal point in the value is accepted by the database program (i.e.: 9.5 weeks).

Response	**Description**
	Number
1	Day(s)
2	Week(s)
3	Month(s)

Table Name: stblLookupLists
LUGroup: GestAgeUnit

GestAgeSource:

Response	**Description**
1	US <14 weeks
2	LMP
3	US between 14 and 27 weeks
4	Standard Neonatal Exam*
5	NS- Not Stated
6	Other

***Note:** The "Standard neonatal exam" means a Ballard or Dubowitz exam.

Table Name: stblLookupLists
LUGroup: DateSource

5.c.i.2. Diagnosis

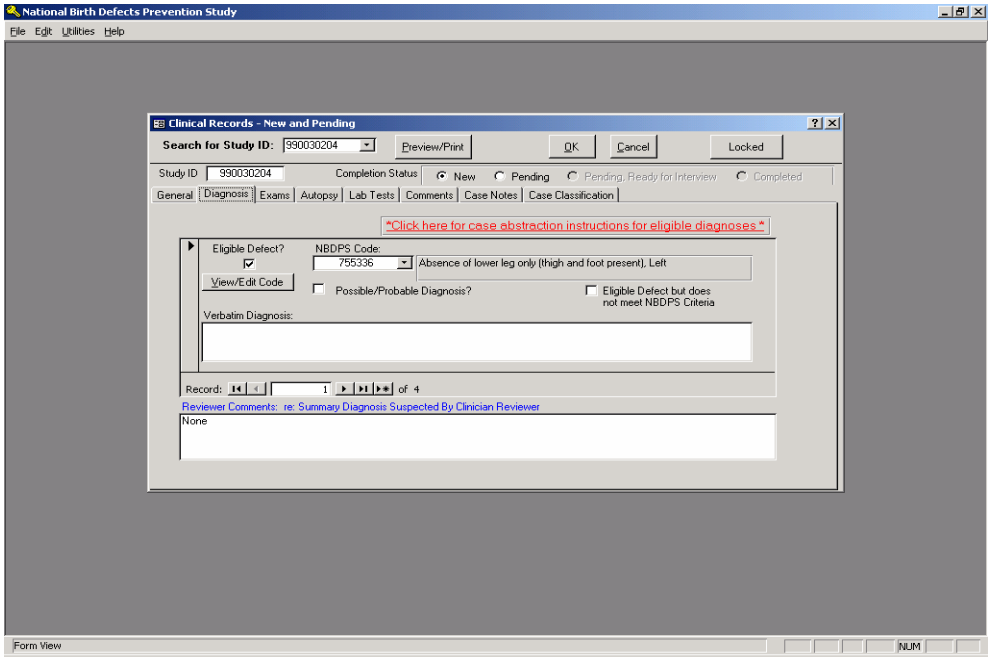
The "Diagnosis" screen is where all the cases' defects are recorded and whether they are eligible. If the "Eligible Defect?" box is checked, then the pull-down menu provides a list of all the NBDPS eligible defects. If the "Eligible Defect? box is not checked, then the pull-down menu provides a list of all the NBDPS codes for non-eligible defects. There is also an option to be checked if the defect is eligible but it does not meet NBDPS criteria (i.e.: when the baby has Muscular VSD and/or Hydrocephalus- NOS.) Note: See "Abstractor's instructions" for Septal Heart Defects to see eligibility exclusions for Muscular VSD.

There is another option to be checked if there is a possible or probable diagnosis of the case. Although each defect is coded, the "Verbatim Diagnosis" is a space provided for the abstractor to enter the verbatim diagnosis obtained from the medical record. This assists the clinical reviewers in their efforts to verify that the correct code was entered, as well as provides others reviewing the case at a later date with additional information that might not be provided by

the code. In addition, the verbatim diagnosis should match the verbal description that appears in the field next to the "NBDPS/ICD-9 Code" drop-down list.

The link in red: "*Click here for case abstractions for eligible diagnoses*" links to a screen that gives an Explanation/Glossary of the eligible defects. It lists birth defect and its definition, types and definitions, ICD-9-CM codes, inclusions, exclusions, additional birth defects, information sources and medical records, defect-specific information to abstract, and additional comments.

The "Reviewer Comments" field is for information pertaining to a baby who is suspected or known to have a sequence, association, or syndrome of unknown etiology (i.e.: VATER association). Cases with syndromes of known etiology (chromosomal abnormalities, single-gene disorders) are excluded from the study. If it is clear that the etiology is known, then the case does not need to be entered into the clinical database. If such a case has been entered, and the clinical reviewer determines that it is not eligible for the study, this information should be entered into "Reasons for Exclusion" field in the "Comments" section/tab. If a case has a syndrome that is suspected to have a chromosome abnormality but a karyotype was not done, the case should be included in the study and a comment regarding the possible known etiology should be entered into this field. Note: This field is not intended to be used for comments back to abstractors or study coordinators.



"Eligible Defect?"

Response	**Description**
Check box……..	True/False
-1……..	Yes (true)
0…….	No (false)

NBDPS Code (Eligible Defects):

Response	**Description**
6-Digit Number……...	NBDPS Code list (776 codes ranging from 658.800 to 759.380).

Query Name: qryBDCodes_Eligible_List

NBDPS Code (Non-Eligible Defects):

Response	Description
6-Digit Number	NBDPS Code list (871 codes ranging from 155.000 to 900.000).

Query Name: qryBDCodes_List

"Possible/Probable Diagnosis?"

Response	Description
Check box	True/False
-1	Yes (true)
0	No (false)

Laterality: (shown for some defects)

Response	Description
0	Laterality, unknown
1	Unilateral, left
2	Unilateral, right
3	Unilateral, side unknown
4	Bilateral
99	NA

Table Name: stblLookupLists
LUGroup: Laterality

Eligible Defect but does not meet NBDPS Criteria:

Response	Description
Check box	True/False
-1	Yes (true)
0	No (false)

Verbatim Diagnosis:

Response	Description
Text	Defect descriptions and summary diagnoses as written in the medical record.

Reviewer Comment:

Response	Description
Text	Summary diagnosis suspected by clinician reviewer.

5.c.i.2.A Diagnosis-

View/Edit Code → Eligible Codes

The **"View/Edit Code"** Button in the "Diagnosis" screen leads to the "Eligible Codes" screen where an eligible defect can be selected from the pull-down menu and its selected defect code is shown at the bottom of the screen. In this screen, there is also an "OK" button as well as a "Cancel" button.

The Explanation/Glossary screen can also be seen from the "Eligible Codes" screen by clicking on its link (in red): "*View Coding Instructions for Selected Defect*". It is not a way to define the codes, but a way to determine the code of a certain defect by filling in the blank field spaces noted below:

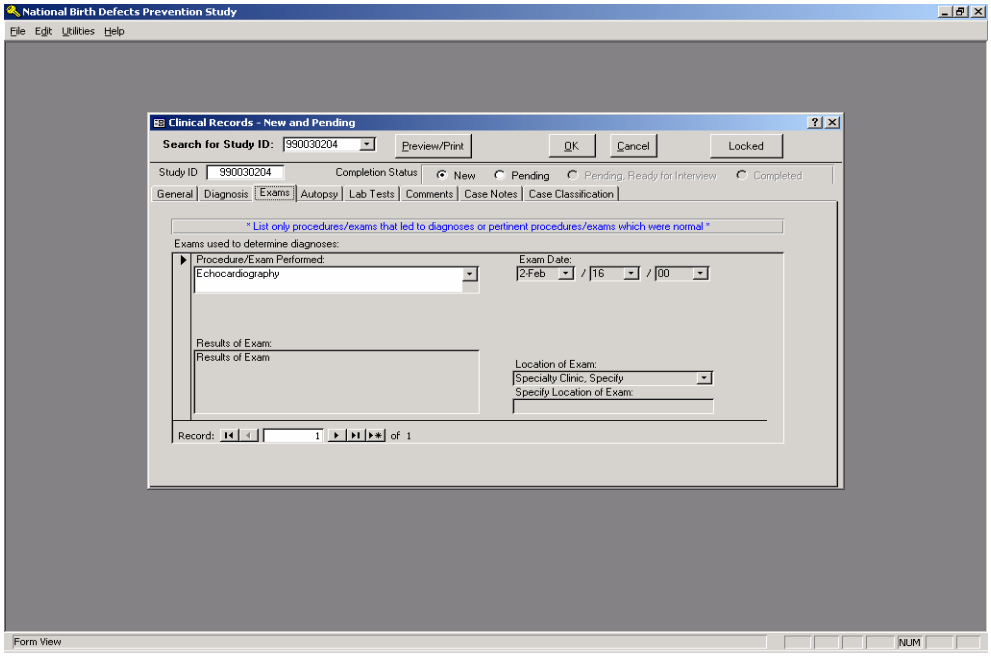
First Three Digits: Description of defect group by the first three digits.
Fourth Digit: Description of defect group for the fourth digit.
Fifth Digit: Description of defect group for the fifth digit.
Sixth Digit: Description of defect group for the sixth digit.

Selected Defect Code:
Shows the defect selected based on the information inputted above regarding digit identification numbers.

5.c.i.3. Exams

The "Exams" section is one of the most important sections for the clinical reviewer. The "Exams" screen lists only procedures and/or exams performed that led to diagnoses or pertinent procedures and/or exams that were normal. It also records the date, location and results of the exams. The aim of this section is to document the available information (positive and pertinent negative) on the cases and the source of that information to verify the defects. For each defect entered (eligible or non-eligible), the exam by which the diagnosis was made must be listed unless the diagnosis was made by an autopsy. Note that some defects need a specific exam to qualiy as a NBDPS case (i.e.: cardiac defect echo).

This section is particularly important in cases where different sources provide conflicting information. Exams that yield pertinent negative results should also be documented. Most babies should have a physical exam/consultation entered since even if there is no defect identifiable on physical exam, it is important to document that a physician examined the infant, and no other defects were noted. Other examples of pertinent negative exams are a renal ultrasound and spine x-rays in a case with a TE fistula. This would be important information in documenting whether other VACTERL association defects were present. For the exams with positive results (resulting in the suspicion or diagnosis of a defect), it is important to include as much information as possible about each exam.



Procedure/Exam Performed:

Response	Description
2	Amniocentesis
3	CVS, chorionic villus sampling
4	Ultrasound, fetal, noncardic
5	Fetal echocardiography by cardiologist
6	PUBS,Percutaneous umbilical blood
7	Fetal surgery
88	Other Prenatal, Specify (e.g., radiography, fetal dye)
99	Physical Exam / Consultation
100	Echocardiography
101	Cardiac catheterization
102	Arteriography
103	Computed tomography (CT)
104	Magnetic resonance imaging (MRI)
105	Radiograph or Xray, plain film
106	Radiograph or Xray w contrast material
107	Radionuclide or radioisotope scan
108	Ultrasound, postnatal, noncardiac
118	Other Postnatal imaging studies, Specify
130	Auditory brainstem response (ABR/BAER)
132	Electrocardiogram (EKG, ECG)
133	Electroencephalogram (EEG)
134	Electroretinogram (ERG)
135	Eye examination under anesthesia
136	Visual evoked response (VER)
148	Other diagnostic procedures: Specify
200	Amputation
201	Anastomosis / Reanastomosis
202	Biopsy
203	Closure
204	Excision / Removal
205	Exploration

206……Graft / Patch
207……Ligation
208……Ostomy
209……Reimplantation
210……Reinsertion
211……Repair / Correction
212……Replacement
213……Revision
214……Shunt
238……Surgery, Other: Specify
239……Surgery, NOS
250……Bracing / Splinting
251……Casting
252……Exchange transfusion
278……Other nonsurgical procedure: Specify

Table Name: stblLookupLists
LUGroup: ExamProc

Specify Type:

Response	**Description**
Specify…….	Specified type of procedure/exam

Control Source: ExamTypeSP

Results of Exam:

Response	**Description**
Text……..	Detailed results of exam

Exam Date: (mm/dd/yyyy)

Note: Response codes, descriptions, and query names for date values are the same as the ones listed above in "LMP Date". (section 5.c.i)

Month:
Query Name: qryMonthList

Day:
Query Name: qryDayList

Year:
Query Name: qryYearList

Date Type:

Response	**Description**
2……...	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

Examiner's Specialty:

Response	Description
2	Attending MD – peds, family doc
3	Attending MD – neonatologist
4	Attending MD – obstetrician
5	Attending MD – other
6	Attending MD – NOS
7	Housestaff MD
8	Nurse pract (PNP)or physician asst (PA)
9	Registered nurse (RN)
10	Attending midwife (CNM)
21	Allergy/immunology MD
22	Behavioral/developmental peds MD
23	Cardiology MD
24	Dermatology MD
25	Endocrinology MD
26	Gastroenterology MD
27	Genetics/metabolism MD
28	Hematology/oncology MD
29	Infectious disease MD
30	Neonatology MD
31	Nephrology MD
32	Neurology MD
33	Pulmonology MD
34	Perinatology MD
40	Surgeon -- general or pediatric
41	Surgeon -- cardiac/thoracic
42	Surgeon -- otolaryngology (ENT)
43	Surgeon – ophthalmology
44	Surgeon -- plastic/reconstructive
45	Surgeon – neurosurgeon
46	Surgeon -- orthopedics/hand
47	Surgeon – urology
48	Surgeon – NOS
88	Other specified specialty
99	NS - Not Stated

Table Name: stblLookupLists
LUGroup: ExamGIvenBy

Specify Specialty:

Response	Description
Specify	Specified specialty of examiner

Control Source: ExamGivenBySP

Location of Exam:

Response	Description
101	Birth Hospital

102.....Referral Hospital
103.....Perinatal/Prenatal Diagnosis Center
104.....Genetics Laboratory
105.....Medical Lab, NOS
106.....Specialty Clinic, Specify
199.....Other, Specify
200.....NS- Not Stated

Table Name: stblLookupLists
LUGroup: ExamGIvenAt

Specify Location of Exam:

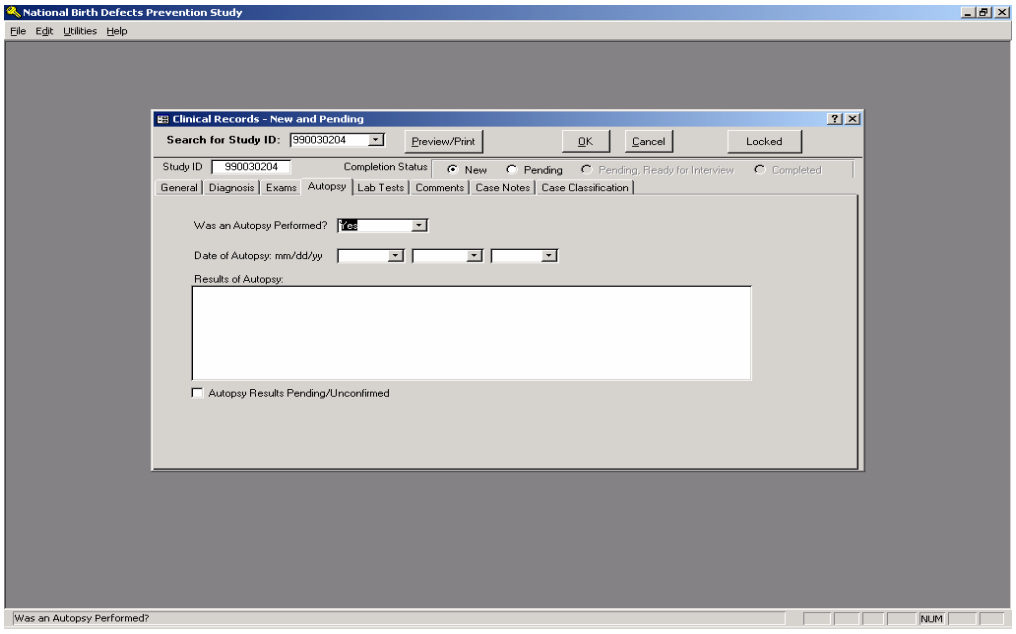
Response	Description
Specify	Specified location of exam*

***Note:** It is important when specifying location of exams NOT to use identifiers (i.e.: names or addresses of hospitals, clinics, or medical facilities).

Control Source: ExamGivenAtSP

5.c.i.4. Autopsy

The "Autopsy" screen records whether or not an autopsy was performed on a stillborn baby or induced abortion. The first item is a gateway field. If "no" is recorded, then all of the other items below are not shown



"Was an Autopsy Performed?"

Response	Description
1	Yes

2.....No
4 .....NA
97.....NS- Not Stated

Table Name: stblLookupLists
LUGroup: YesNoNA

Date of Autopsy: *(mm/dd/yyyy)*

Note: Response codes, descriptions, and query names for date values are the same as the ones listed above in "LMP Date". (section 5.c.i)

Month:
Query Name: qryMonthList

Day:
Query Name: qryDayList

Year:
Query Name: qryYearList

Date Type:

Response	Description
2……...Three Part Date	

Table Name: stblLookupLists
LUGroup: DateType

Results of Autopsy:

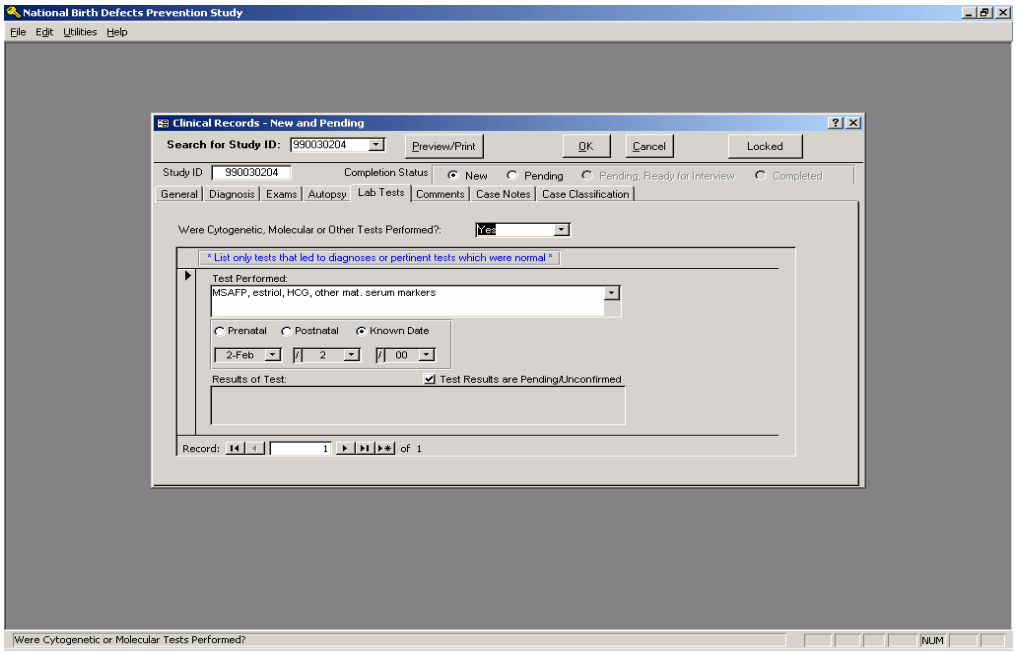
Response	Description
Text……..Detailed results of autopsy recorded from pathology reports/medical records or abstractor's notes.	

Autopsy Results Pending/Unconfirmed

Response	Description
Check box……..True/False	
-1……..Yes (true)	
0……No (false)	

5.c.i.5. Lab Tests

The "Lab Tests" screen lists only tests that led to diagnoses or pertinent tests that were normal. It records which lab tests were performed, its date and its results. The first item is a gateway field. If "no" is recorded, then all of the other items below are not shown.



"Were Cytogenic, Molecular or Other Tests Performed?"

Response	Description
1	Yes
2	No
97	NS- Not Stated

Table Name: stblLookupLists
LUGroup: YesNoDK

Test Performed:

Response	Description
1	Chromosome analysis, specify tissue
2	FISH/ISH -fluorescent in situ hybridization, specify tissue
3	MSAFP, estriol, HCG, other mat. serum markers
4	Fetal AFP or AchE
5	Other biochemistries or enzyme assays, specify
6	DNA or molecular studies
7	TORCH titers
88	Other, Specify

Table Name: stlbLookupLists
LUGroup: CytoProc

Specify Test Name:

Response	Description
Specify	Specified test name

Control Source: TestNameSp

Test Date:

Response	Description
1	Prenatal
2	Postnatal
3	Known date

Table Name: stblLookupLists
LUGroup: TestDateGrp

Known Date: *(mm/dd/yyyy)*

Note: Response codes, descriptions, and query names for date values are the same as the ones listed above in "LMP Date". (section 5.c.i)

Month:
Query Name: qryMonthList

Day:
Query Name: qryDayList

Year:
Query Name: qryYearList

Date Type:

Response	Description
2	Three Part Date

Table Name: stblLookupLists
LUGroup: DateType

Results of Test:

Response	Description
Text	Detailed results of test

Control Source: TestResults

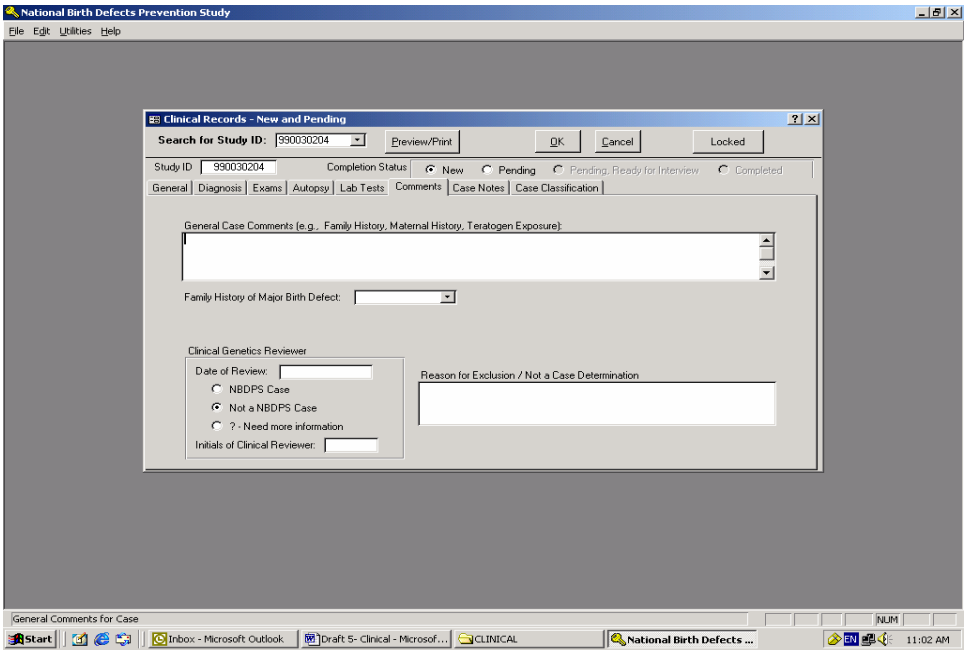
"Test Results are Pending/Unconfirmed"

Response	Description
Check box	True/False
-1	Yes (true)
0	No (false)

5.c.i.6. Comments

The “Comments” screen is where general comments are recorded pertaining to family history, maternal history, possible teratogenic exposures, type of delivery, drugs taken at birth, and/or any maternal exposure to cigarette smoke, alcohol, and/or drugs.

There is a space below for the clinical genetics reviewer to record the date of review, what type of case it is, and the reviewer’s initials. There is also a text box provided for the reviewer to indicate the reason for exclusion of a certain case linked to the tracking system.



General Case Comments:

Response	**Description**
Text	General comments for case

Family History of Major Birth Defect:

Response	**Description**
1	Yes
2	No
97	NS- Not Stated.

Table Name: stblLookupLists
LUGroup: YesNoDk

“Was this”:

Response	**Description**
1	the same defect
2	a different defect
97	NS- Not Stated.

Table Name: stblLookupLists
LUGroup: FamHistSame

Clinical Genetics Reviewer

Date of Review: *(mm/dd/yyyy)*

Response	Description
MM/DD/YYYY	Month/Day/Year

Control Source: SubmissionDate

Date Type:

Response	Description
1	Date Data Type

Table Name: stblLookupLists
LUGroup: DateType

Eligibility Status:

Response	Description
1	NBDPS Case
2	Not a NBDPS Case
3	? –Need More Information

Table Name: stblLookupLists
LUGroup: EligStatus

Specify Additional Information Required for Eligibility Status:

Response	Description
Text	Additional information required for eligibility status

Initials of Clinical Reviewer:

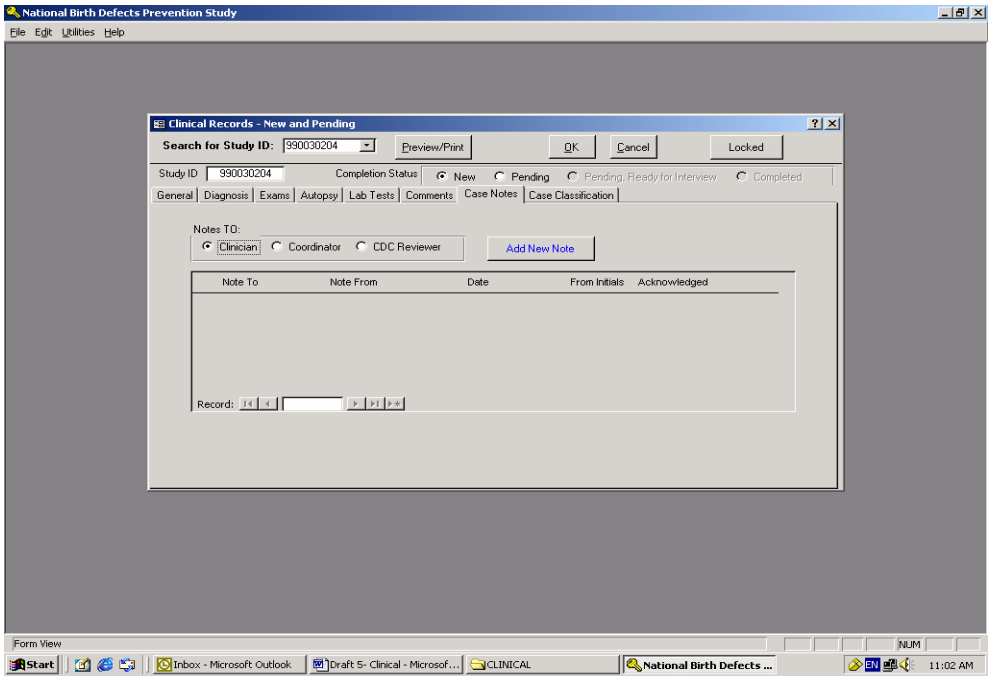
Response	Description
Text	Reviewer's Initials

Reason for Exclusion/Not a Case Determination:

Response	Description
Text	Reviewer's explanation.

5.c.i.7. Case Notes

The “Case Notes” screen is where notes can be written and shared back and forth among the clinicians, the coordinators and the CDC reviewers. The database features a tool that allows one to browse just the case notes. The notes contain the following information: to whom the note is directed, whom it is from, the date it was written, the initials of whom wrote it, and whether it was acknowledged by the receiver/reader.



Notes To:

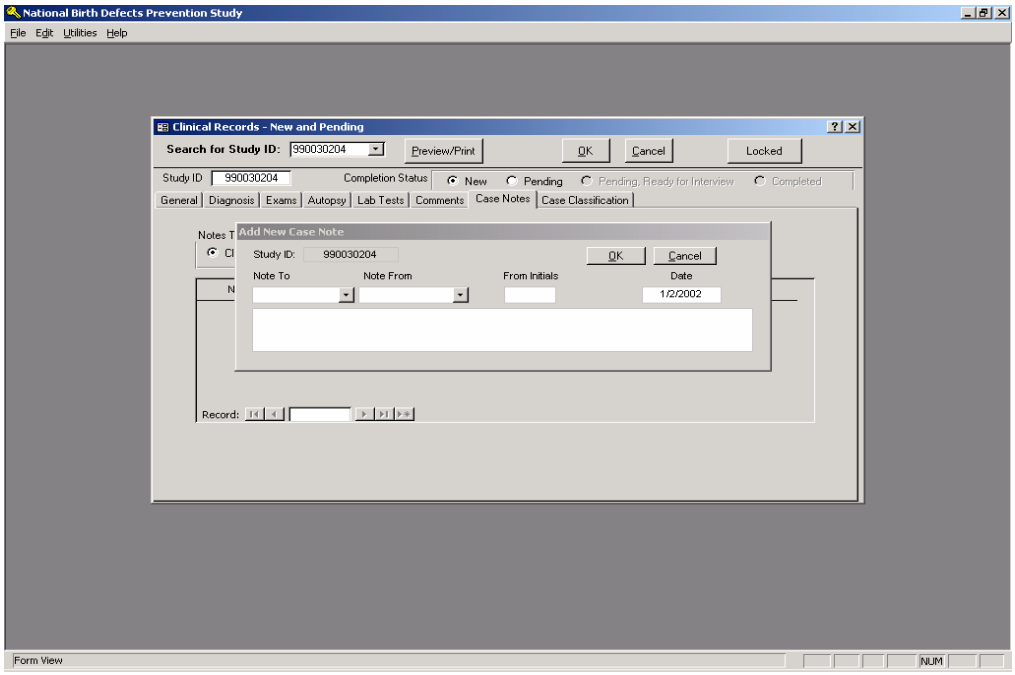
Response	**Description**
1	Clinician
2	Coordinator
3	CDC Reviewer

Table Name: stblLookupLists
LUGroup: NoteSubjects

5.c.i.7.A Case Notes

Add/New Note → Add New Case Note

The “Case Notes” screen also has an “Add/New Note” button that goes to another screen “Add New Case Note”. The “Add New Case Note” screen contains the study ID, and the same information as above: Note To, Note From, Date (automatically imputed), and From Initials. It also has an “OK” button and a “Cancel” button.



Notes To:

Response	**Description**
1	Clinician
2	Coordinator
3	CDC Reviewer

Table Name: stblLookupLists
LUGroup: NoteSubjects

Notes From:

Response	**Description**
1	Clinician
2	Coordinator

Table Name: stblLookupLists
LUGroup: NoteSubjects

Date:

Note: Automatically inputted from database.

From Initials:

Response	**Description**
Text	Initials of person who wrote the notes.

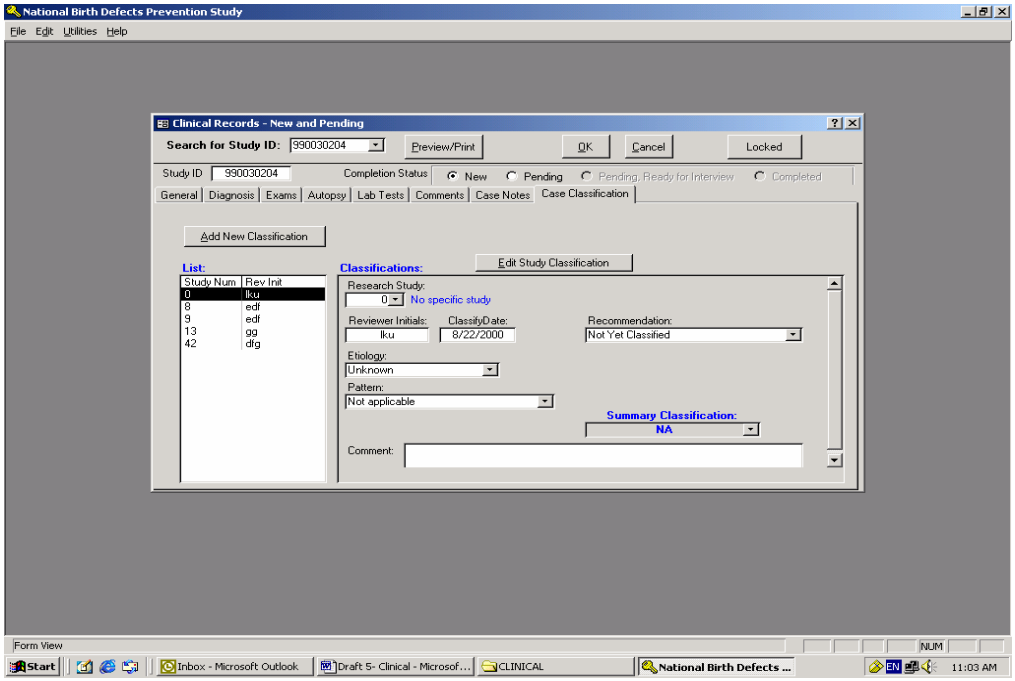
Acknowledged:

Response	Description
Check box	True/False
-1	Yes (true)
0	No (false)

5.c.i.8. Case Classification

The "Case Classification" screen is only to be used for specific studies. It lists the research study number (which represents a specific study listed under the pull-down menu in “research study” in this screen) and the reviewer’s initials. The reviewer classifies individual cases for particular studies, including the classification date, the initials of the reviewer, recommendations, etiology, pattern, summary of classifications, and comments or recordings.

There is an “Edit Study Classification” button that allows the reviewer to edit any of the above fields. This button then changes to “Save Study Classification” which allows the reviewer to save any editorial comments or recordings The comments section is for a particular summary/syndromic diagnosis made by the reviewer or other verbatim information.



List:

Response	Description
Study Number	List of study ID numbers

Response	Description
Reviewer’s Initials	List of reviewer’s initials beside the study ID numbers.

Table Name: tblCaseRecords_Classification

Research Study:

Note: See Appendix …..CI-1 for response codes (Research Study ID Numbers) and descriptions (Research Study Description).

Table Name: tblResearchStudies

Reviewer's Initials:

Response	Description
Text	Reviewer's Initials.

Classify Date:

Note: Automatically inputted from database.

Recommendation:

Response	Description
1	Include in study
2	Exclude from study
3	Not yet classified

Table Name: stblLookupLists
LUGroup: StudyInclude

Etiology:

Response	Description
6	Unknown
4	Teratogens
5	Uterine factors
1	Single gene (not NBDPS)
2	Chromosomal (not NBDPS)
3	Continuous gene (not NBDPS)

Table Name: stblLookupLists
LUGroup: Etiology

Exclude Criteria:

Response	Description
1	Defect secondary to defect not included in current study.
2	Syndrome (unknown etiology) strongly suspected.
3	Method of diagnosis excluded for present study.

Table Name: stblLookupLists
LUGroup: ExcludeCriteria

Specify:

Response	Description

Text……..Specified exclude criteria.

Pattern:

Response	Description
1	Solitary major defect (isolated)
2	Sequence
3	Solitary major + minors
4	Multiple major (previously described pattern), Specify
5	Multiple major (not previously described pattern)
6	Additive
9	Not applicable
10	Unknown

Table Name: stblLookupLists
LUGroup: Pattern

Pattern Specify:

Response	Description
Text	Specified pattern

Summary Classification:

Response	Description
0	NA
1	Isolated
2	Multiple
3	Syndrome

Table Name: stblLookupLists
LUGroup: SummaryClassify

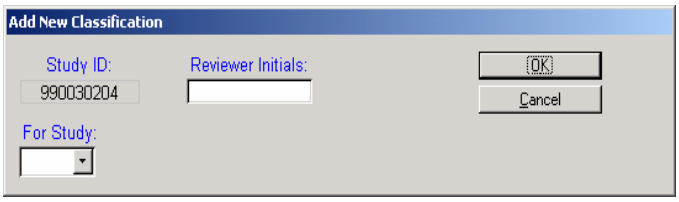
Comment:

Response	Description
Text	Comments made by reviewer.

5.c.i.8.A Case Classification

Add/New Case Classification → Add New Classification

The “Case Classification” screen has an “Add/New Case Classification” button which provides the study ID and allows the reviewer to select a new case classification to the study from a pull-down menu. The reviewers also write their initials, and there is an “OK” button and a “Cancel” button. The figure below will appear within the “Case Classification” screen:



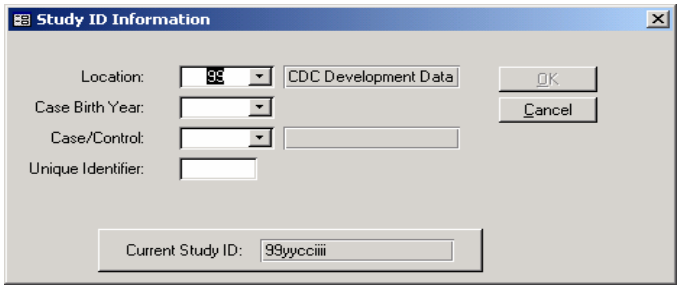
5.c.ii. Section B: "Completed"

The "Completed" button leads to the "Clinical Records –Completed" screen, where the data manager can search for a completed study ID number. Like the "New and Pending" section, there are 8 tabs for cases that lead to other screens within the "Completed" section: "General", "Diagnosis", "Exams", "Autopsy", "Lab Tests", "Comments", "Case Notes", and "Case Classification". For controls, only 3 tabs are shown: "General", "Case Notes", and "Case Classification". All of these screens will show the "Search for Study ID" field, the "Study ID" field, the "Preview/Print" button, the "OK" button, the "Cancel" button, the "Locked" button and the "Completion Status" field which marks the case is "completed" from the options: "New", "Pending", "Pending/Ready for Interview", or "Completed". The "Completed" screen and the ones within, are the same as those for the "New and Pending". Please see the above section (6.a.) "New and Pending" for response codes, descriptions, and any other information regarding table name, LU Groups, and queries for the screens in this section (6.b) "Completed".

5.c.iii. Section C: "Add New Record"

The "Add New Record" button leads to the "Study ID Information" screen. Where the data manager can add a new study ID number. There are four fields in this screen. These fields are combined to make a new study ID number composed of information regarding: location of the study (CBDRP site), case birth year, whether it is a case/control/practice, and a unique identifier to that index baby. At the bottom of this screen, the new ID or "Current Study ID" is then given to that index baby. This screen also has an "OK" button and a "Cancel" button.

After the new study ID is created, the data manager can then input all the needed information into the "General" screen in the "New and Pending" section. The figure below will appear once the "Add New Record" button is selected.



5.c.iii.1 Study ID Information

Location:

Response	Description
Number	CBDRP site number
10	Arkansas
11	California
12	Iowa
13	Massachusetts
14	New Jersey
15	New York
16	Texas
17	CDC/Atlanta
99	CDC Development Data

Table Name: stblSiteInfo

Case Birth Year:

Response	Description
YYYY	Birth year of case index
1996	1996
---	---
2003	2003
97	NS- Not Stated

Table Name: stblLookupLists
LUGroup: YearList
Query Name: qryYearList

Case/Control:

Response	Description
1	Case
2	Control
3	Practice

Table Name: stblLookupLists
LUGroup: CaseControl

Unique Identifier:

Response	Description
4-Digit Number	Number given to specific index baby.

Current Study ID:

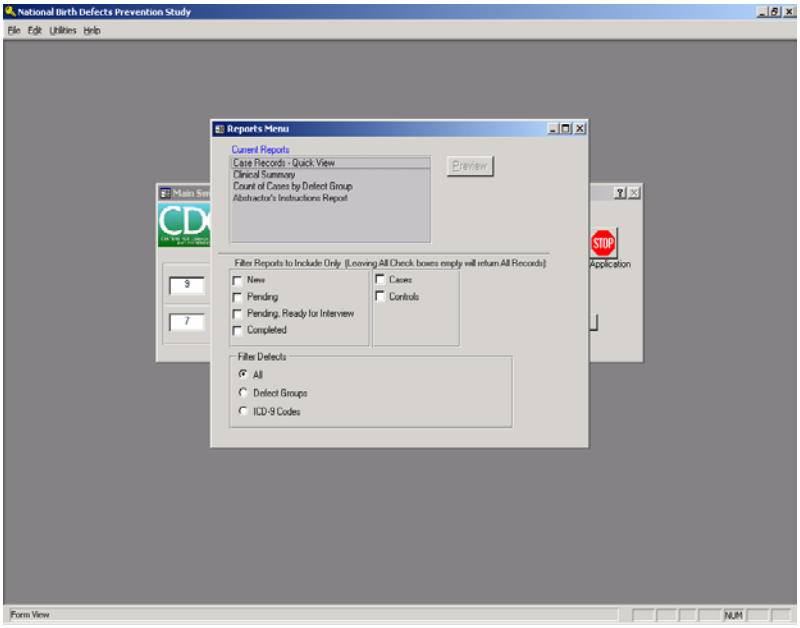
Response	Description
Number	Study ID Number given to specific index baby.

5.c.iv. Section D: "Reports"

The "Reports" button leads to the "Reports Menu" screen. The "Reports Menu" generates reports of the case records, clinical summary, count of cases by defect group, and the abstractor's instructions report (which is the same as the Explanation/Glossary of defects found under the Diagnosis section of the Clinical database).

5.c.iv.1 Reports Menu

To view the reports, select from: "Case Records", "Clinical Summary", "Count of Cases by Defect Group", and the "Abstractor's Instructions Report", then press the "Preview" button. The "Case Records" and "Clinical Summary" reports can be filtered to include only certain criteria such as: new, pending, pending/ready for interview, and completed cases. The reports can be classified as cases and/or controls. The reports can also be filtered by defects: all (defects), defected groups (a pull-down menu provides a list to choose from), or NBDPS Codes (a pull-down menu of NBDPS codes provides a list to choose from).



"Case Records –Quick View" Report:

The "Case Records –Quick View" report lists the study ID, whether it is case or control, infant's date of birth, gender, pregnancy outcome, and date the report was last reviewed. It distributes this information according to whether it is considered to be "new", "pending", or "completed".

"Clinical Summary" Report:

The "Clinical Summary Information" report lists the study ID, the date of birth or term of pregnancy, gender, pregnancy outcome, gestational age, and known age. It also shows diagnosis information on whether it is an eligible defect or possible/probable defect. It shows the NBDPS code and label and the verbatim diagnosis.

"Count of Cases by Defect Group" Report:

The "Count of Cases by Defect Group" report lists the defect groups and a count of how many cases have that specific defect, as well as a total number of defects in the study.

"Abstractor's Instructions" Report:

The "NBDPS Abstractor's Instructions" report is the same as the one linked to the "Eligible Codes" from the "View/Edit Code" button in the "Diagnosis" section of the Clinical Database. It lists birth defects and their definitions, types of birth defects and their definitions, ICD-9-CM codes, inclusions, exclusions, additional birth defects, information sources and medical records, defect-specific information to abstract, and additional comments.

Defect Groups:

Note: See Diagnosis section (6.a.ii) under "NBDPS Code / ICD-9CM Code" for response codes, description and code table names of defect groups.

ICD-9 Codes:

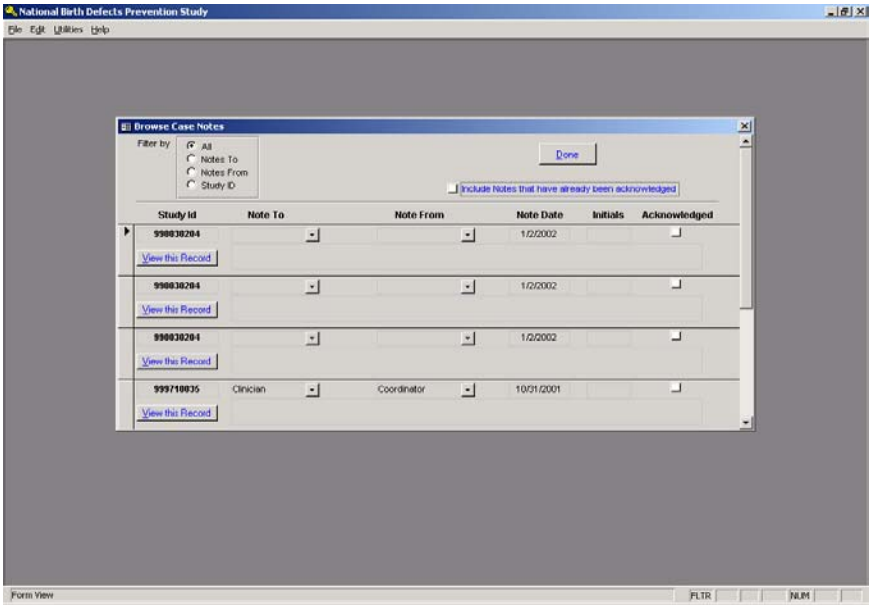
Note: See section 6.a.ii (Diagnosis) under "NBDPS Code / ICD-9CM Code" for response codes, description and code table names of ICD-9 codes.

5.c.v. Section E: "Browse Case Notes"

The "Browse Case Notes" button leads to the "Browse Case Notes" screen, where notes can be browsed by filtering: "all" (includes all case notes), "notes to" (case notes to certain people/positions: clinicians, coordinators, or CDC reviewer), "notes from" (case notes from certain people/positions: clinicians, coordinators, or CDC reviewer), and "study ID" (case note records from a pull-down menu of study ID numbers). There is also a checkbox option: "Include notes that have already been acknowledged".

5.c.v.1 Browse Case Notes

The screen lists notes by study ID, who it is to ("note to"), whom it is from ("notes from"), note date, initials of who wrote the note, and a checkbox of whether the note has been acknowledged or not. Under the "study ID" number, there is a "View This Record" button that leads to the "Clinical Records" screen for that specific study ID.



Filtered By:
(This is an "Option Group" or "Radio Button", only one choice can be selected).

Response	**Description**
1	All
2	Notes To
3	Notes From
4	Study ID

Position:
If filtered by "Notes To" or "Notes From"

Response	**Description**
1	Clinician
2	Coordinator
3	CDC Reviewer

Table Name: stblLookupLists
LUGroup: NoteSubjects

Records with Notes:
If filtered by "Study ID"

Response	**Description**
Number	Study ID number –lists all related information to specified study ID.

Table Name: tblCaseRecords

“Include notes that have already been acknowledged”

Response	**Description**
Check box……..	True/False
-1……..	Yes (true)
0…….	No (false)

5.c.vi. Section F: “Direct ID Search”

The “Direct ID Search” field allows the study ID to be inputted into the blank field space and then by pressing the “Find Now” button, the database will look for the clinical information regarding that specific study ID. The search will lead to the “Clinical Records” screen for the specified study ID.
